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WATER TECHNOLOGIES

A primer on water quality for sterile processing

WATER QUALITY DEFINED

Water, which can exist as a solid, liquid, or vapor, consists of one atom of oxygen and two atoms of hydrogen bonded together by their shared electrons. In terms of water purity, anything that is not an H+ or OH- ion is considered a contaminant or impurity.

The Environmental Protection Agency (EPA) identifies contaminants to regulate in drinking water to protect public health.[1] The Agency sets regulatory limits for the amounts of certain contaminants in water provided by public water systems. Local public water systems treat water to these standards to make it potable (safe to drink). However, despite this treatment, water can become re-contaminated with chemicals and microorganisms as it is distributed through the municipality's piping infrastructure. This contamination can be problematic for many applications that use this potable water. Sterile Processing in hospitals is one such application.

WATER QUALITY IS IMPORTANT IN STERILE PROCESSING

Water quality is an important consideration in all stages of medical device reprocessing. The primary objective of medical device reprocessing is to ensure that a device is safe for patient use and does not cause an adverse event in the patient.[2,3]

It is important that personnel who reprocess medical devices (or use them in procedures) understand how the quality of the facility's water can have an impact on the reprocessing equipment, as well as the devices and instruments themselves. It is also important that personnel recognize that the quality of water should be regularly monitored to ensure that the control measures in place are working properly.

WATER TREATMENT

Water treatment includes a collection of water purification devices and associated piping, pumps, valves, and gauges that together produce purified water of a specified quality and deliver it to the point of use. Water purity is an indication of the extent to which impurities (e.g., dissolved organic and inorganic solids and microbial contaminants, ionic, and chemical) have been removed.

[1] United States Environmental Protection Agency. https://www.epa.gov/dwstandardsregulations; 2018
[2] AAMI TIR34: 2014/*2017—Water for the reprocessing of medical devices
[3] ANSI/AAMI ST79:2017—Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Note: This primer is intended to provide a general overview of the importance of water quality for sterile processing, as well as the AAMI TIR34: 2014/(R)2017 guidelines. It is not intended act as a substitute for healthcare personnel reading the full AAMI TIR34 document, additional industry, guidelines, or medical device manufacturers' Instructions for Use (IFU).

ADVERSE EFFECTS OF POOR WATER QUALITY

Water impurities can have adverse effects to medical device reprocessing.

Adverse effects to the product:

- Corrosion, pitting, scaling
- Biomass build-up
- Increase microbial load or endotoxin content

Adverse effects to the process:

- Decreased effectiveness of detergents
- Degradation of the water system (biofouling or scaling)

Adverse effect to the patient:

- Infection
- Toxicity

It is important that Sterile Processing personnel understand the water quality issues that can contribute to adverse patient events and be aware of some of the gross indicators that suggest that there may be problems with the water quality. Monitoring water quality is a process meant to confirm that control strategies are working properly.

In the preparation of water for use in medical device reprocessing, two general characteristics need to be considered:

- The microbial level in water
- The inorganic and organic components of water

Ensuring adequate water quality in device reprocessing requires collaboration between the personnel who reprocess medical devices and the personnel who establish and maintain the water treatment system.

AAMI TIR34: 2014/(R)2017

In order to educate and provide guidance to healthcare facility personnel, the Association for the Advancement of Medical Instrumentation (AAMI) publishes a comprehensive Technical Information Report (TIR) called TIR34—Water for the reprocessing of medical devices.

This living document is intended to provide guidelines on the quality of water that should be used in each stage of medical device reprocessing for each category of medical device. It also includes annexes that provide technical information to water maintenance personnel (i.e., personnel such as Facilities Engineering/ Management who are involved in water treatment and distribution in the facility) to guide them in configuring and monitoring water treatment systems.

More specifically, AAMI TIR34: 2014/(R)2017 includes the following:

- Covers the quality of the water used to clean, rinse, disinfect, and sterilize medical devices.
- Defines water types on the basis of hardness, pH, microorganism levels, endotoxin levels, and other characteristics. The following topics are covered:
    - Importance of water quality and effective water treatment
    - Categories of water quality for medical device reprocessing
    - Selection of water quality
    - Water treatment systems
    - Monitoring of water quality
    - Strategies for microorganism control
    - Personnel considerations
    - Continuous quality improvement
    - Troubleshooting water quality issues
- Provides definitions of terms and a bibliography
- Annexes contain technical details pertaining to water treatment and monitoring for the benefit of water maintenance personnel

AAMI ST108: WATER FOR THE PROCESSING OF REUSABLE MEDICAL DEVICES

The current AAMI TIR34 guideline will soon be replaced with a new standard, AAMI ST108: Water for the Processing of Reusable Medical Devices. The AAMI ST108 standard is currently in development and will have a strong emphasis on proper water system design, monitoring, testing and maintenance. Since this standard is coming soon, it is important that your SPD is adequately prepared.

AAMI TIR 34: Key Highlights

CATEGORIES OF MEDICAL DEVICES

Device Category[1]	Definition	Examples	Minimum Disinfection Level
Critical	Device that enters sterile tissues or the vascular system	Surgical instruments, transfer forceps, cardiac catheters, biopsy forceps, etc.	Sterilization
Semi-critical	Device that comes in contact with non-intact skin or mucous membranes	Non-invasive, flexible fiber optic endoscopes, endotracheal and aspirator tubes, respiratory therapy equipment, etc.	High Level Disinfection
Non-critical	Device that comes in contact with intact skin but not mucous membranes	Bedpans, reusable anesthesia masks, blood pressure cuffs	Low Level or Intermediate Level Disinfection

Note: As defined by the Spaulding Categories (CDC, 2008)

CATEGORIES OF WATER QUALITY FOR MEDICAL DEVICE REPROCESSING

Water Category	Definition
Utility water	Water that comes from the tap that may require further treatment. Used for flushing, washing, rinsing.
Critical water	Water that is extensively treated to ensure microorganisms and inorganic and organic materials are removed. Used for the final rinse or steam generation.

RECOMMENDED LEVELS OF WATER QUALITY FOR MEDICAL DEVICE REPROCESSING

Specifications	Utility Water[1] Flushing/Washing/Rinsing	Critical Water Final Rinse[2]/Steam
Hardness (mg/L)	< 150[3]	< 1
Conductivity (µS/cm)	< 500	< 10
pH[4]	6–9	5–7
Chlorides (mg/L)	< 250	< 1
Bacteria (cfu/ml)	< 10[5]	< 10
Endotoxin (EU/ml)	< 20[5]	< 10

1 This is the quality of water that might come from the tap but might need some form of treatment to achieve these specification.
2 If this is the final rinse prior to sterilization of a critical device.
3 If hardness is greater than 150 mg/l, a water softener is recommended unless used for washing and the cleaning chemistry is capable of handling higher levels of hardness.
4 For boiler-treated steam, most boilers are treated to maintain a pH of 7.5 or 8.5. Any treatment of water that goes into boilers should be in accordance with the sterilizer and boiler manufactures' written IFU.
5 After high-level disinfection.

ABOUT EVOQUA WATER TECHNOLOGIES

With more than 65 local service branches in the U.S. and Canada, Evoqua provides unparalleled service coverage and support to hospitals and medical centers all across North America. We recognize that when it comes to patient care—whether it's critical laboratory testing or sterilizing surgical instruments—uptime is everything and keeping you operational is mission critical. With nearly 90% of the U.S. population located within a two-hour drive from an Evoqua service branch, we are well positioned to ensure your high purity water needs are met 24 hours a day, seven days a week. Whether your hospital is privately owned or not-for-profit, a critical care facility, part of a larger network, university-affiliated, large or small, Evoqua has the right water treatment solutions to help you keep your facility operating optimally.

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